

EXHIBIT R

Message

From: Close, Michael [Michael.Close@mallinckrodt.com]
Sent: 10/10/2014 1:50:29 PM
To: Foster, Susan [Susan.Foster@mallinckrodt.com]
Subject: Distribution Prezo
Attachments: ARD Distribution presentation.pptx

Hi Susan,

Here is what I was planning to cover in some variation next week. Brian Smith asked me to do a 45-minute presentation on the distribution model and Specialty Pharmacy for the group. About 20 slides very high level overview planned.

Have a great weekend and see you next week!

Mike





Distribution Channel Overview



Critical Success Factors for Today's Prezo



Articulate:

- Specialty Distribution and Distribution Models in the marketplace
- Walk thru Acthar® Gel from a 3PL, current distribution model, and alternate model perspective
- Specialty Pharmacy Marketplace overview
- Discuss Selecting an SP partner, Pharmacy/Medical Benefit , Any Willing Provider statue

What is a Specialty Pharmaceutical?



Distribution of brand name specialty drugs and biologicals that do not fit into the pharmaceutical wholesaler model and product mix

- Shipping and handling requirements of the medication (i.e. frozen products)
- Associated with complex illnesses, clinical management and close patient monitoring
- Provider and patient administered
- Expensive with high medical cost potential
- Small or well-defined patient populations, remote areas of administration, disease education, involved BI
- Limited inventory or manufacturing challenges exist
- Distributed through restricted provider network
- Reimbursed under medical benefits



It is projected that by 2020, 9 of the 10 best-selling drugs by revenue will be specialty drugs, compared with 3 drugs in 2010 and 6 in 2013.

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Specialty pharmaceuticals (Provider and Patient administered) are brand-name or generic drugs for patients undergoing intensive therapies for such chronic, complex illnesses as multiple sclerosis, rheumatoid arthritis, and cancer. Patients taking specialty therapies may require disease education, frequent dosing adjustments, and intensive clinical monitoring. Specialty drugs are also much more expensive than traditional pharmaceuticals. Patients typically need help researching and obtaining insurance coverage for specialty medications.

Albumin

Anti-hemophilic factors

Biologicals

Biosurgery products

Hyperimmunes

Injectables and infused products

Intravenous immune globulin (IVIG)

Nephrology products

Oncology products

Orals

Plasma protein fraction

Rheumatology products

Urology products

Vaccines

Specialty Product Example



Specialty Criteria	Product Profile Example
Price	Annual cost of drug therapy >\$12,000
Size of patient population	Orphan <200,000; Ultra-orphan <6,000
Complexity of health plan design	Medical or pharmacy benefit; prior authorization; step edits; failure to other therapies; required testing
Complexity of administration	HCP administered injection or infusion; reconstitution prior to injection or infusion; cold chain brought to room temperature prior to administration
Complexity of disease state	Focused screening and/or monitoring of treatment

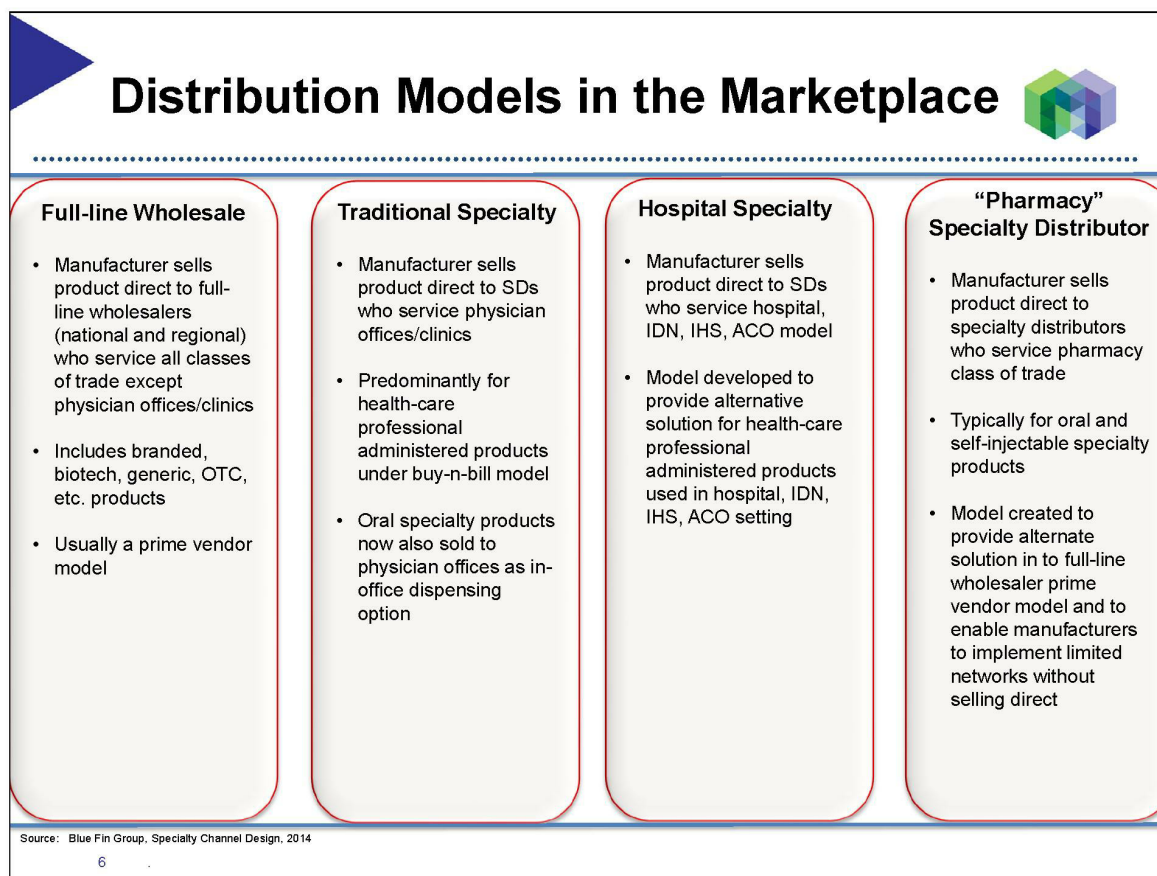
Source: Blue Fin Group, Specialty Channel Design, 2014

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Pharma companies continue to invest in research to develop new treatments in specialty area. According to a new report by PhRMA, there are nearly 800 cancer medications and vaccines either in clinical trials or awaiting review by the FDA

Specialty Products –

Unlike specialty products in a limited specialty pharmacy network, some products are in open distribution and can be dispensed by any licensed pharmacy. All pharmacies have access to open distribution products, because they can be purchased from a full-line wholesaler. Therefore, wholesalers inventory, sell, and distribute these specialty products as they would traditional drugs. Examples include Copaxone (Teva), Humira (AbbVie), and Sovaldi (Gilead Sciences.) This is why we typically get request from Specialty Pharmacies to be added to our network. They take a success breeds success mindset. However, there are specific differences in payor contracting for the lives for orphan drug(s) like Acthar® Gel.



Full-Line

Retail Pharmacy, hospitals, (e.g., Diabetes, Hypertension, CV, lifestyle drugs) - There are 5,700 hospitals in the U.S. 70 Hospitals generally do not need or want large on-site inventories of drugs and therefore rely on wholesalers as a purchasing channel. Drug wholesalers generate about one-sixth of their revenues from sales to hospital pharmacies. (See Exhibit 2, on page 7.)

Specialty - Oncology, RA (Remicade) - Thus, in the buy-and-bill system, the provider is responsible for:

- ☐ Ordering and purchasing the drug from a specialty distributor
- ☐ Managing drug inventory at the practice
- ☐ Prescribing and administering the drug to a patient
- ☐ Submitting reimbursement claims for a drug and related professional services
- ☐ Collecting a patient's coinsurance or copayment for all services

The specialty distributor is responsible for:

- ☐ Purchasing products from manufacturers
- ☐ Negotiating the drug's cost with the provider
- ☐ Delivering the specialty drug to the provider's location
- ☐ Collecting payment from the provider

Hospital Specialty - A hospital pharmacy typically purchases specialty pharmaceuticals from a full-line wholesaler, under its preferred vendor contract, rather than from a specialty distributor. These sales can occur via a health-system GPO (described above) or via a purchasing relationship between a hospital and a wholesaler, especially for the many specialty drugs that are not on a GPO contract.

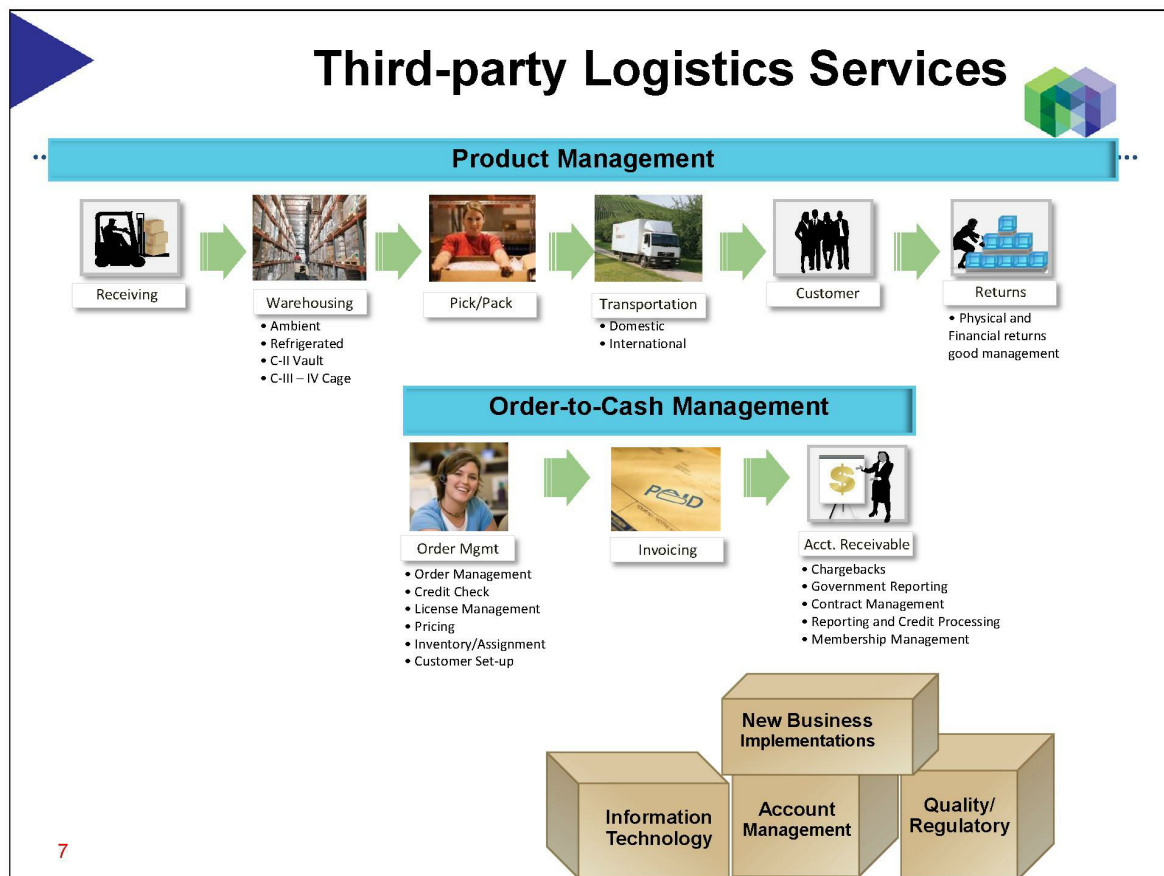
A small volume of specialty drugs is sold directly by manufacturers to hospital pharmacies. Some manufacturers are also developing channel strategies in which a specialty distributor sells product to a hospital, which orders the product via its prime vendor full-line wholesaler. These arrangements are enabled by the corporate ownership relationships between full-line wholesalers and specialty distributors.

Many specialty drugs are administered in hospital outpatient departments. These sites are owned and operated by a hospital or system but can be located at the hospital facility or at a different location. Over time, specialty drug administration has been

shifting from physician offices/clinics to hospital outpatient departments.

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Pharmacy SD -our model to be touched on later

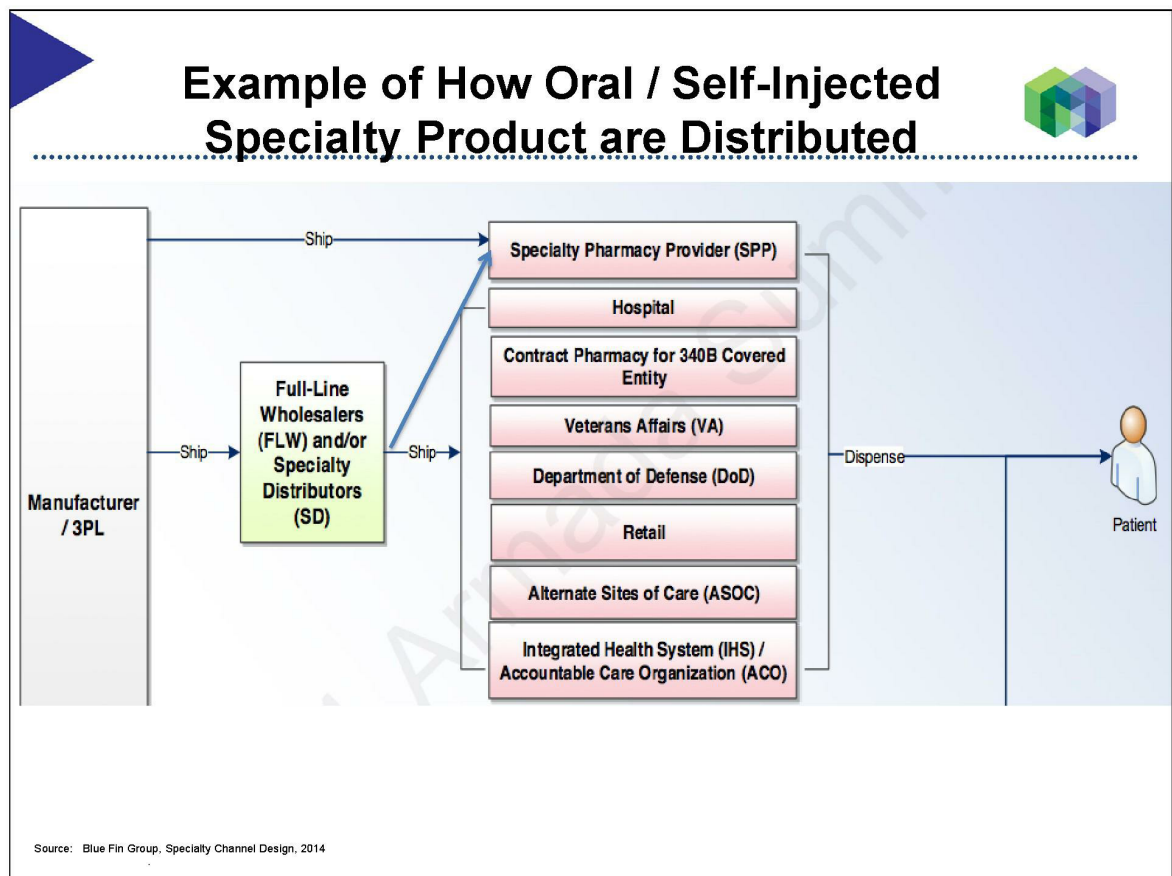


3PL – Can be done in-house or out-sourced to companies with core capabilities in pick/pack/ship warehouse operations, outbound distribution, and order-to-cash management on a fee-for-service basis: Mck, CAH, ABC(ICS), Omni-Care, UPS

Typically smaller pharma/biotech companies choose this route due to lack of core capabilities.

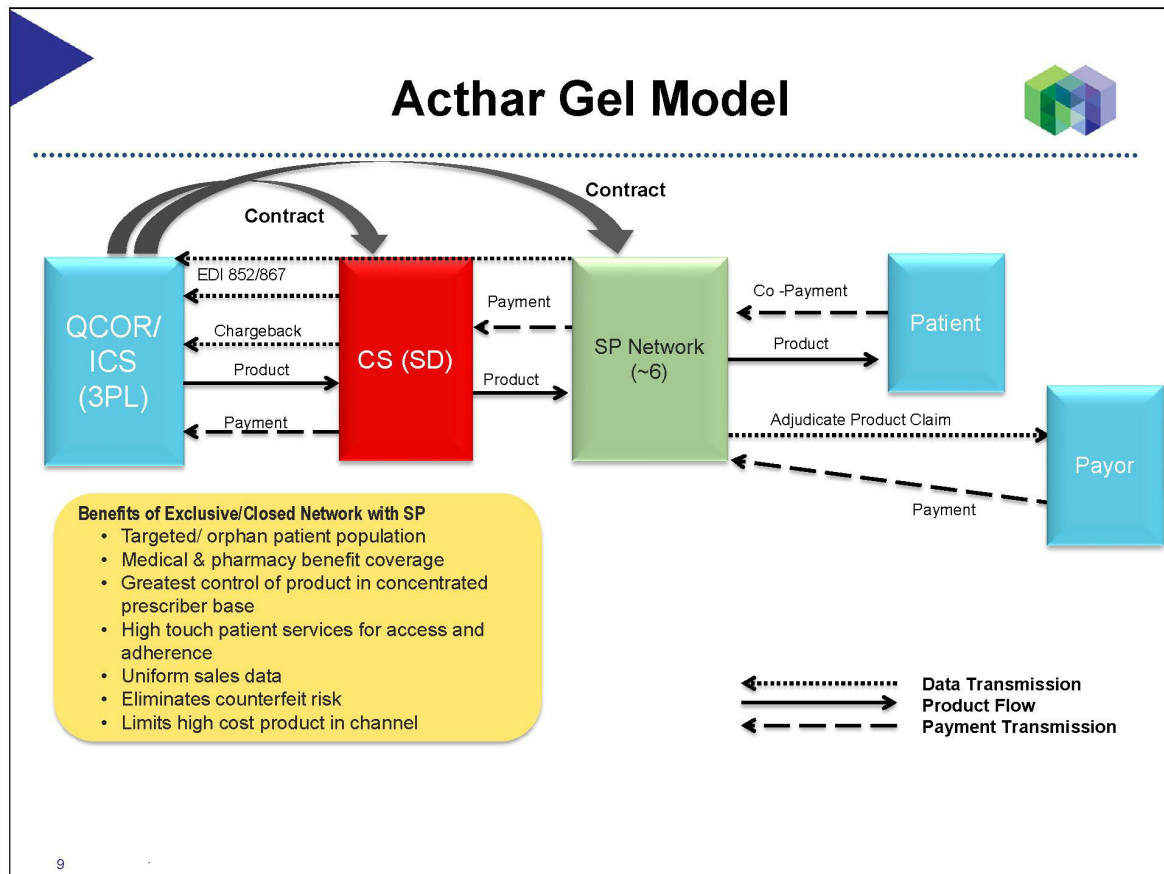
Can also provide regulatory services around state licensing, VAWD accreditation, assistance with ensuring product integrity during storage & shipping

“Verified Accreditation Wholesale Distribution”



In light of previous discussion, this is a typical supply chain for how an oral/self-injected product enters the channel and is distributed. Manufacturers tend to select SDs over Wholesalers because of channel management strategy and cost. Some SDs have a stronger presence in hospitals (CAH), others in physician offices (ABC and MCK) still others in DOD (MCK Pharmaceutical Prime Vendor). If the manufacturer does not include all three SDs, they have to drop-ship which can be cumbersome.

So patient population, cost of drug, route of administration and channel strategy will determine number of participants.



Challenges/Opportunities with this Model:

Challenges

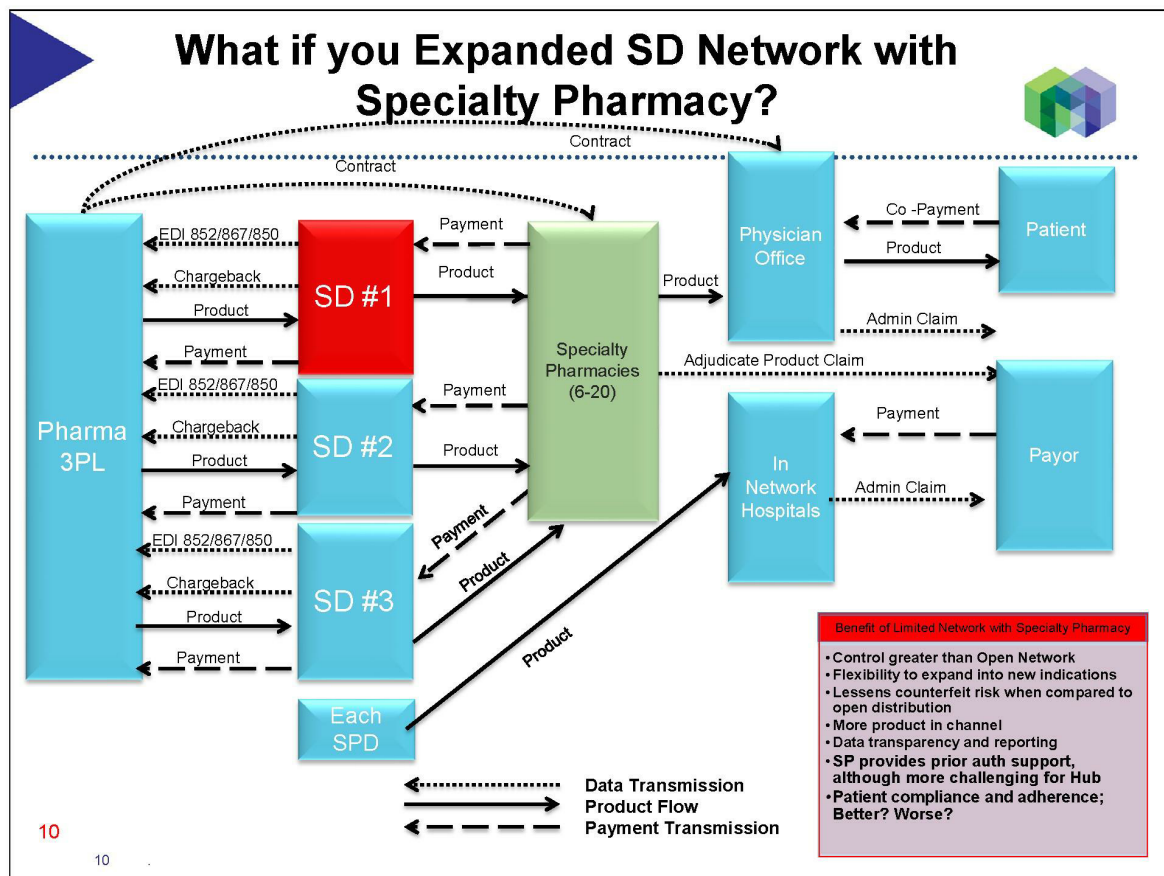
IPA/TPA, Self-funded employer groups

Opportunities

Eliminating SD

852 – Inventory

867 – sales dispensing

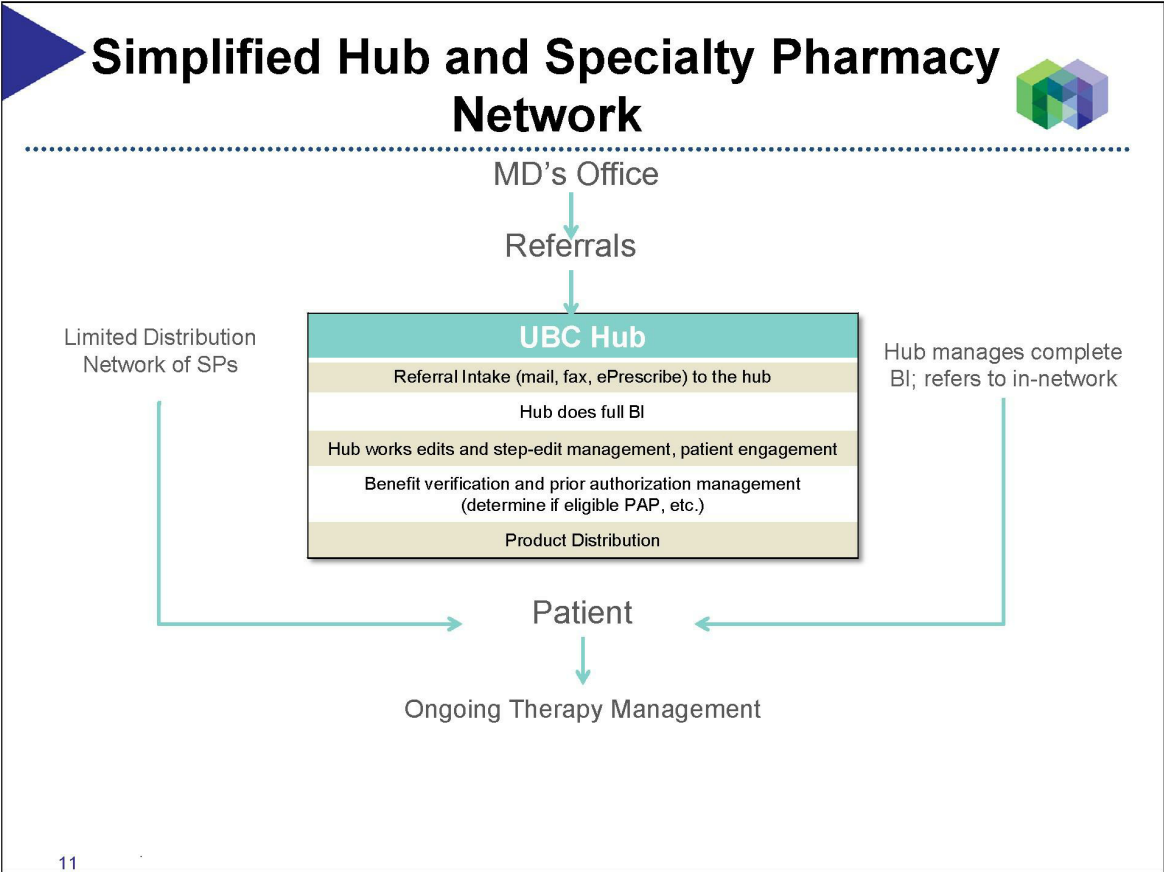


Why wouldn't this work for Acthar® Gel?

Dilution of patient

More product in channel

Difficult to ensure uniform consistency from SP to SP



What is a Specialty Pharmacy's Role in the Channel?



Specialty pharmacies are distinct from traditional pharmacies in coordinating many aspects of patient care and disease management. They are designed to:

- Efficiently deliver medication with special handling, storage, and distribution requirements for chronic diseases
- Improve clinical and economic outcomes for patients with complex, often chronic and rare conditions, with close contact and management by clinicians
- Provide patient education, help ensure appropriate medication use, promote adherence, and attempt to avoid unnecessary costs
- Help patients locate resources to provide financial assistance with co-pays. Manufacturers often collaborate with Specialty Pharmacies to provide these services
- Work efficiently with Manufacturer Hub Model

Specialty Pharmacy Value Proposition



The high cost, high management of specialty pharmacy demands the close coordination of activity and patient management among the key stakeholders

PATIENT	PHYSICIAN	PAYER	PHARMACEUTICAL MANUFACTURER
Service Expectation <ul style="list-style-type: none"> •Toll-free, 24-hour clinical support •Benefits verification •Direct home delivery •Internet community •Friendly call-center 	Service Expectation <ul style="list-style-type: none"> •Clinical extension of the office •Compliance management •Customized dose delivery •Reimbursement coordination •Patient education services •Coding and billing assistance 	Service Expectation <ul style="list-style-type: none"> •Competitive pricing •Customized programs (e.g. disease treatment management and clinical support) •Reduction in wasted drug •Dedicated payer/sales support • Access to LDD •Accreditation (URAC, ACHC) 	Service Expectation <ul style="list-style-type: none"> •Shipping and delivery <ul style="list-style-type: none"> –Nationwide distribution –Special handling –Overnight delivery •Patient and office assistance <ul style="list-style-type: none"> –Direct patient interaction –Patient/physician reimbursement coordination –Clinical trial drug delivery –Indigent care / patient assistance programs (PAPs) •REMS execution
Measurement <ul style="list-style-type: none"> •Improved outcomes •Increased satisfaction 	Measurement <ul style="list-style-type: none"> •Time savings •Patient satisfaction •More patients 	Measurement <ul style="list-style-type: none"> •Cost savings •Member satisfaction 	Measurement <ul style="list-style-type: none"> •Patient satisfaction •Prescriber satisfaction •Improved patient access •Regulatory compliance •Increase sales



Examples of Pharmacies Dispensing Specialty Pharmaceuticals



Specialty Pharmacy Provider Alignment Categories*

**Not a comprehensive list, for illustrative purposes only*

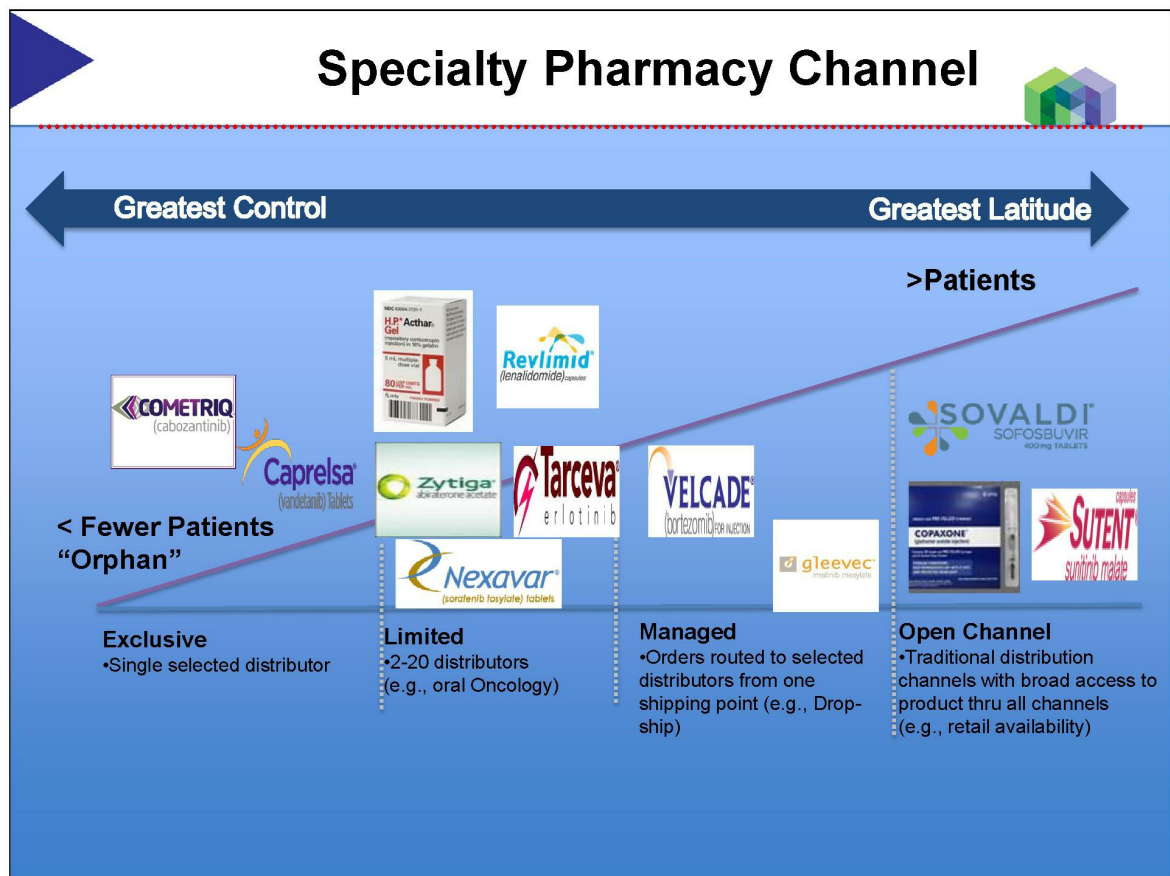
Payer Aligned	Retail Aligned	Wholesaler Aligned	Independent	IHS / IDN / ACO
 CIGNA  Aetna	 Walgreens Specialty Pharmacy	 US Bioservices AmersourceBergen Specialty Group	 Biologics Optimizing oncology care	 GEISINGER
 RightSource  OPTUMRx	 Walmart Save money. Live better.	 OncologyRx Care Advantage™	 Diplomat Specialty Pharmacy  Onco360 ONCOLOGY PHARMACY SOLUTIONS	 Henry Ford HEALTH SYSTEM  MAYO CLINIC
 exactus PHARMACY SOLUTIONS Experts in pharmacy management	 AXIOM THE PHARMACY  RITE AID	 Omnicare Specialty Care Group ACS Advanced Care  OncoSourceRx A Cardinal Health Specialty Pharmacy	 Avella Specialty Pharmacy  ASTELL Astell	 excelera  FAIRVIEW
 PBM Aligned  CVS CAREMARK  accredo				

Despite the many market participants, pharmacy market share for dispensing specialty drugs is highly concentrated. The SP's of three companies, --ESI, CVS Caremark, and Walgreens—account for about two-thirds of revenues from pharmacy-dispensed specialty drugs.

Source: Blue Fin Group, Specialty Channel Design, 2014

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I think I have spoken to everyone of these



Cometriq (Exelixis) and Caprelsa (AZ) are exclusive; Nexavar (Bayer) is in a limited distribution agreement. Companies with small patient populations, narrow clinical indications, along with things like REMS requirements look for a smaller or exclusive SP channel. This gives them the ability to partner with an SP who can provide better clinical, financial and support service access to the drug.

What makes our current SP network work?



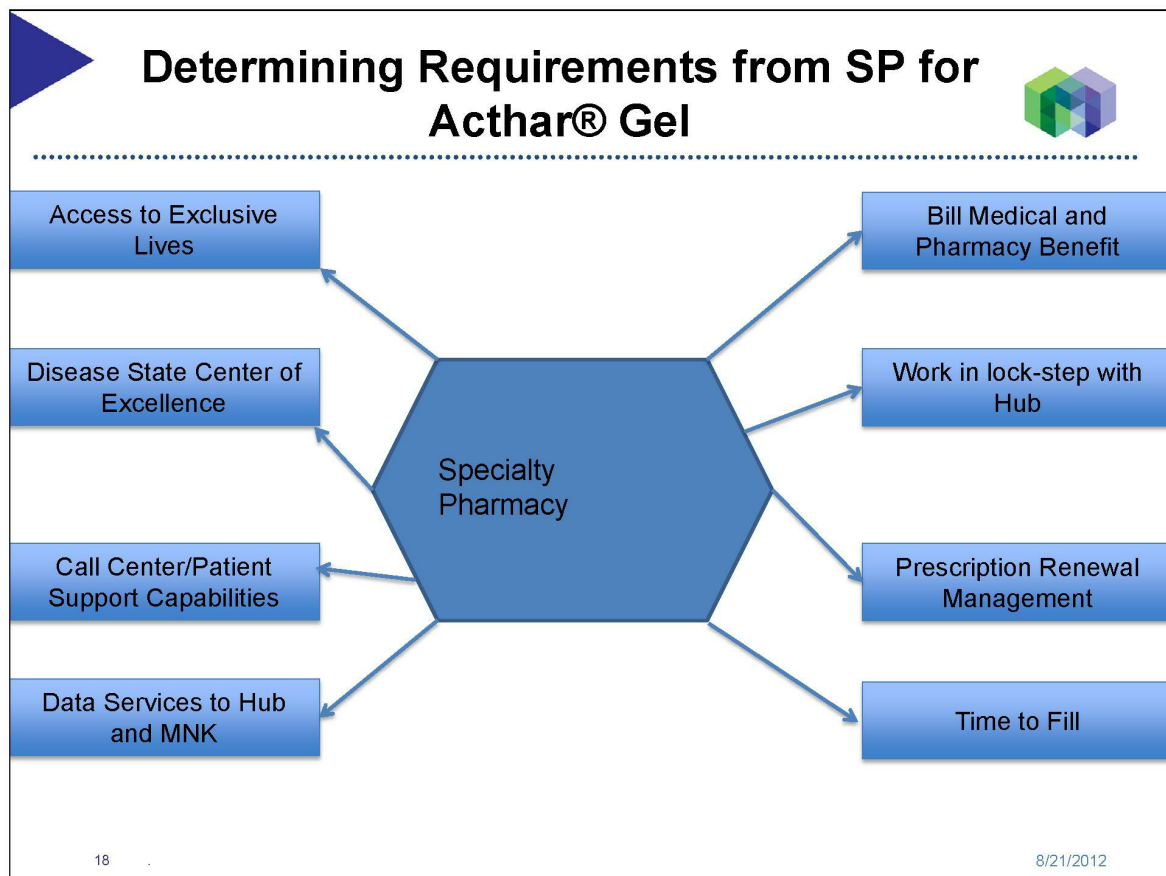
- Access to Lives by current SPs. Stated another way, they are either owned by health plan or have a contractual relationship
- Billing under medical and pharmacy benefit
- Work efficiently with our hub
- ▶ Cost of our drug
- ▶ Size of Acthar® Gel patient population

Challenges:

- ▶ IPA/TPA's, fully-capitated MDs, self-funded employer groups

Opportunities:

- ▶ Sell from 3PL to Specialty Pharmacies direct
- ▶ As part of Any Willing Provider provision, triage Medicare Part D or Medicaid to selected SPs in our network.



Why is this important for a drug like Acthar Gel?

SP will not get refill

Call Center/Patient Support Capabilities

Product Counseling

Refill Reminders

Prescriber Letters/Supplemental Materials,

Referrals to Financial and PAP

Dedicated Product team to include program supervisor

Communication between us, the hub and QBRs

AE reporting and Patient Complaints

Data Services to Hub and MNK - Database and reports - Dispense reports, Inventory, go/no void reports for referrals, Dispense updates from Hub

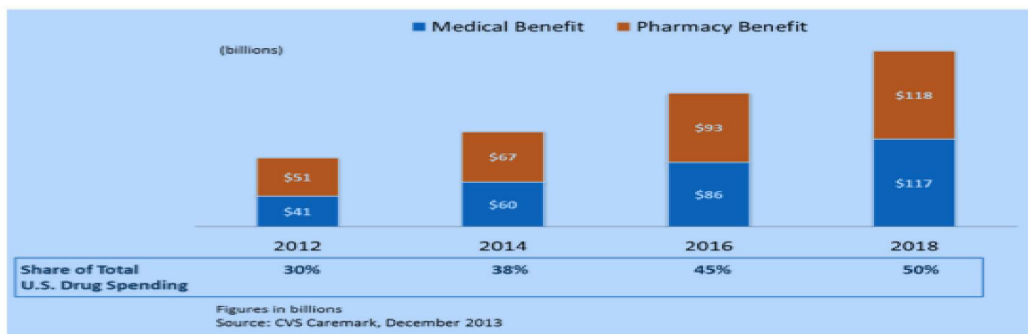
Pharmacy vs. Medical Benefit



There are also large variations existing within drug classes and condition categories with the route of drug administration typically determining whether it's the medical or pharmacy benefit that covers the specialty drug. For example:

- Pharmacy benefit: Typically covers self-administered oral, injectable and inhaled drugs
- Medical benefit: Typically covers drugs that are injected or infused by a health care professional in the doctor's office, hospital out-patient center, free-standing infusion center/clinic or by a mobile infusion therapy provider at home

Total Spending on Specialty Drugs, by Benefit Type, 2012-2018



What are Any Willing Provider Law(s)?



Snapshot:

- ▶ "Any willing provider laws require managed care plans to accept any qualified provider who is willing to accept the terms and conditions of a managed care plan. These laws do not require managed care plans to contract with all providers. However, they do require managed care plans to explicitly state evaluation criteria and ensure "due process" for providers who wish to contract with the plan." (NCSL)

- These 22 states have some form of Any Willing Provider Law:
- AL, AK, CO, CT, DE, FL, GA, ID, IL, IN, IA, KY, LA, MA, MS, MO, MT, NE, NH, NJ, NC, ND, OK, RI, SC, SD, TN, TX, UT, VA, WI, WY

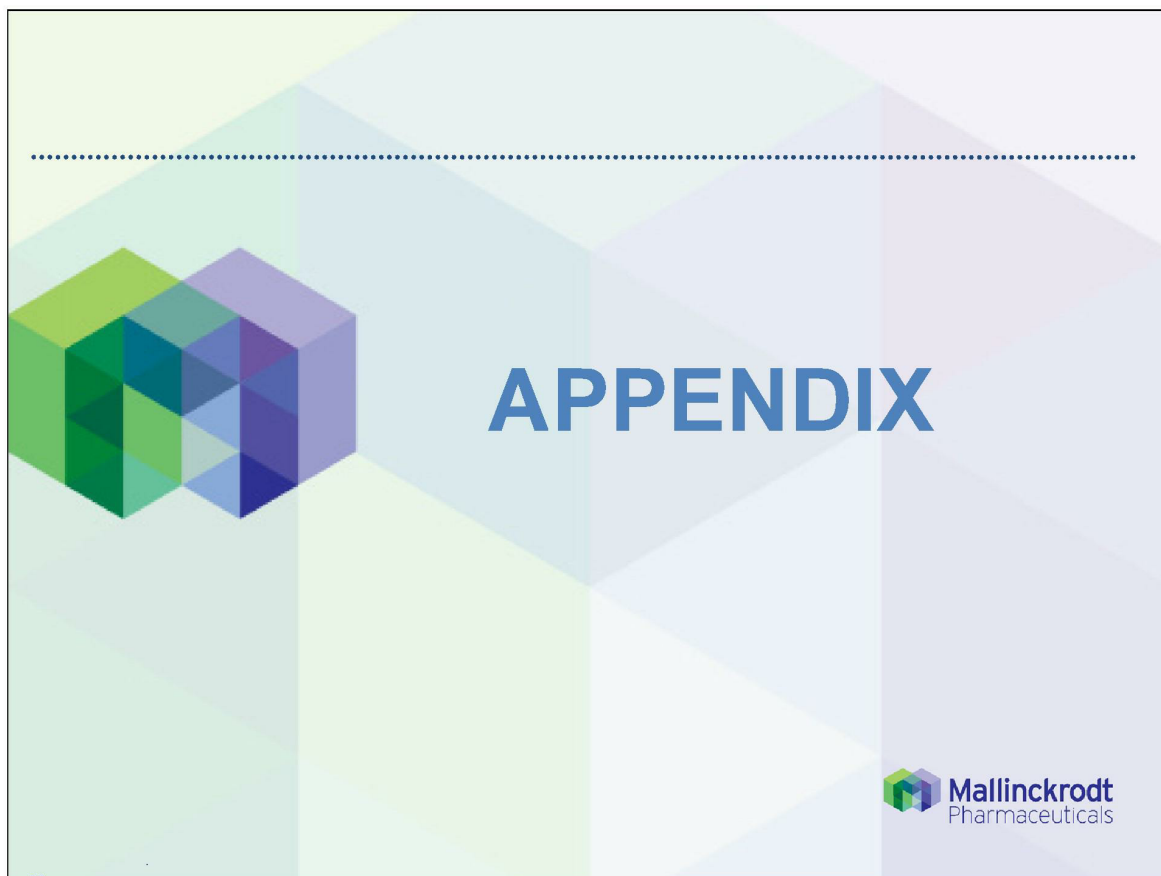


This is a great opportunity for us to partner with SPs who have a high concentration of Med-D lives or a presence (Walgreens) with Payor/PBMs in Med-D in AWP.

Key Take Away Summary



- Distribution Models in the marketplace are varied and can take on various looks to fit the channel management strategy and best outcome for patient
- Specialty Pharmacy are becoming primarily controlled by Payors and PBMs although there are very good independent regional Specialty pharmacies in the marketplace
- Ultimately, manufacturers are going to choose the model that has the fewest access barriers to the patient, gives them visibility thru data agreements into the drug and patient experience, and provides the most efficacy outcome



Exclusive distribution supply chain



Offers controlled distribution through **one** specialty distributor

PROS

- Offers quick access to products with orphan indications, small or well defined patient populations or has reduced inventory by reducing the risk of out-of-date product, counterfeit issues and controls supply chain volume
- Using a sole-source specialty distributor provides uniform 852 / 867 data.
- Provides the ability to scale as indications expand. Small number of patients; requires controlled setting
- Establishing performance standards with one distributor is easier to manage and expand from when indications advance

CONS

- Requires educating pharmacy channels on ordering and access process.

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What is a Specialty Pharmacy?



- Specialty pharmacies are distinct from traditional pharmacies in coordinating many aspects of patient care and disease management. They are designed to:
 - A specialty pharmacy typically provides more extensive care management, counseling, case management and coordination of care with other stakeholders involved in a patient's treatment. Efficiently deliver medication with special handling, storage, and distribution requirements
 - Improve clinical and economic outcomes for patients with complex, often chronic and rare conditions, with close contact and management by clinicians
 - Provide patient education, help ensure appropriate medication use, promote adherence, and attempt to avoid unnecessary costs
 - Help patients locate resources to provide financial assistance with co-pays. Manufacturers often collaborate with Specialty Pharmacies to provide these services

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Specialty Pharmacy Landscape

Specialty drugs, including biologics, treat complex chronic and life-threatening medical conditions. They are different from traditional drugs in how they are developed and manufactured, and often require special handling and administration, as well as significant patient education, monitoring and follow-up. Side effects from the use of specialty drugs can be more frequent and serious than those of traditional drugs.

HUB with Specialty Pharmacy Limited Network

GOAL: Referral management thru Hub and **a few** specialty pharmacies

PROS

- Essential for medical coverage where a full BI is needed
- Control over referral triage, reimbursement support and management
- Support can be perceived to be higher with this model in the provider community

CONS

- Costly model to operate and manage for manufacturers and SPPs
- Double work – after hub does front-end BI and triages referral, SPP repeats the work unless specific SOPs are put in place.
- Rx volume can flow to SPPs first even when HUB is in place due to SP's own sales force, aka, "feet on the street"

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Better economies of scale for you the manufacturer

Product and patient support can be perceived to be higher with this model in the provider community leading to better script referral for first and existing competitor patients

Better coordinated reimbursement support and PAP/Co-pay program and patient experience.

Nursing support

More timely data collection

Limited distribution networks for specialty products are particularly frustrating to hospital and retail providers. In an attempt to control both inventory and data, manufacturers may opt for a closed distribution system. The advent of programs such as risk evaluation and mitigation strategies, often associated with high-risk/high-cost drugs, has created the need for extra data collection. From the point of view of the manufacturers, limiting the distribution of drugs increases compliance and the consistency of data collection. -

Examples of Pharmacies Dispensing Specialty Pharmaceuticals



Ownership	Examples
Pharmacy Benefit Managers	
Drugstore Chains	
Health Plans	
Wholesalers	
Physician Practices	
Hospital Systems and Group Purchasing Organizations	
Regional/Independent Specialty Pharmacies	
Independent Retail Pharmacy Networks	

Source: Pembroke Consulting research

Despite the many market participants, pharmacy market share for dispensing specialty drugs is highly concentrated. The SP's of three companies, --ESI, CVS Caremark, and Walgreens—account for about two-thirds of revenues from pharmacy-dispensed specialty drugs.

Pembroke 2014-15 Economic Report on Pharmaceutical Wholesale and Specialty Distributors, Exhibit 15

Specialty Product Distribution



- Albumin
- Anti-hemophilic factors
- Biologicals
- Biosurgery products
- Hyperimmunes
- Injectables and infused products
- Intravenous immune globulin (IVIG)
- Nephrology products
- Oncology products
- Orals
- Plasma protein fraction
- Rheumatology products
- Urology products
- Vaccines

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